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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,938	01/31/2001	Margo Haygood	1133.010US1	3910

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EXAMINER
KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
1652	9

DATE MAILED: 09/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/775,938	HAYGOOD ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *66-89* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

1. In a preliminary amendment filed on January 31, 2001 (Paper No. 7), Claims 1-65 were cancelled and Claims 66-89 were added. Thus, Claims 66-89 are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121. The Examiner has divided the inventions first into SuperGroups, then Groups (Groups 1-92), for ease in explanation of distinctness. However, a **GROUP** must be elected, not a SuperGroup, in response to the instant Office action.

SuperGroup A: Claims 66-74, 86-89, drawn to nucleic acid molecules, classified in class 536, subclass 23.1.

Group 1. SuperGroup A related to SEQ ID NO:9.
Group 2. SuperGroup A related to SEQ ID NO:11.
Group 3. SuperGroup A related to SEQ ID NO:13.
Group 4. SuperGroup A related to SEQ ID NO:15.
Group 5. SuperGroup A related to SEQ ID NO:17.
Group 6. SuperGroup A related to SEQ ID NO:19.
Group 7. SuperGroup A related to SEQ ID NO:21.
Group 8. SuperGroup A related to SEQ ID NO:23.
Group 9. SuperGroup A related to SEQ ID NO:25.
Group 10. SuperGroup A related to SEQ ID NO:27.
Group 11. SuperGroup A related to SEQ ID NO:29.
Group 12. SuperGroup A related to SEQ ID NO:30.
Group 13. SuperGroup A related to SEQ ID NO:31.
Group 14. SuperGroup A related to SEQ ID NO:32.
Group 15. SuperGroup A related to SEQ ID NO:33.
Group 16. SuperGroup A related to SEQ ID NO:34.
Group 17. SuperGroup A related to SEQ ID NO:35.
Group 18. SuperGroup A related to SEQ ID NO:36.
Group 19. SuperGroup A related to SEQ ID NO:37.

SuperGroup B: Claims 75-79, drawn to polypeptides, classified in class 435, subclass 183.

Group 20. SuperGroup B related to polypeptides encoded by SEQ ID NO:11.
Group 21. SuperGroup B related to polypeptides encoded by SEQ ID NO:13.
Group 22. SuperGroup B related to polypeptides encoded by SEQ ID NO:15.
Group 23. SuperGroup B related to polypeptides encoded by SEQ ID NO:17.
Group 24. SuperGroup B related to polypeptides encoded by SEQ ID NO:19.
Group 25. SuperGroup B related to polypeptides encoded by SEQ ID NO:21.
Group 26. SuperGroup B related to polypeptides encoded by SEQ ID NO:23.
Group 27. SuperGroup B related to polypeptides encoded by SEQ ID NO:25.
Group 28. SuperGroup B related to polypeptides encoded by SEQ ID NO:27.
Group 29. SuperGroup B related to polypeptides encoded by SEQ ID NO:29.
Group 30. SuperGroup B related to polypeptides encoded by SEQ ID NO:30.
Group 31. SuperGroup B related to polypeptides encoded by SEQ ID NO:31.
Group 32. SuperGroup B related to polypeptides encoded by SEQ ID NO:32.
Group 33. SuperGroup B related to polypeptides encoded by SEQ ID NO:33.
Group 34. SuperGroup B related to polypeptides encoded by SEQ ID NO:34.
Group 35. SuperGroup B related to polypeptides encoded by SEQ ID NO:35.
Group 36. SuperGroup B related to polypeptides encoded by SEQ ID NO:36.
Group 37. SuperGroup B related to polypeptides encoded by SEQ ID NO:37.

SuperGroup C: Claim 80, drawn to methods for making polyketides using isolated polypeptides that biosynthesize polyketides, classified in class 435, subclass 76.

Group 38. SuperGroup C related to a polypeptide encoded by SEQ ID NO:11.
Group 39. SuperGroup C related to a polypeptide encoded by SEQ ID NO:13.
Group 40. SuperGroup C related to a polypeptide encoded by SEQ ID NO:15.
Group 41. SuperGroup C related to a polypeptide encoded by SEQ ID NO:17.
Group 42. SuperGroup C related to a polypeptide encoded by SEQ ID NO:19.
Group 43. SuperGroup C related to a polypeptide encoded by SEQ ID NO:21.
Group 44. SuperGroup C related to a polypeptide encoded by SEQ ID NO:23.
Group 45. SuperGroup C related to a polypeptide encoded by SEQ ID NO:25.
Group 46. SuperGroup C related to a polypeptide encoded by SEQ ID NO:27.
Group 47. SuperGroup C related to a polypeptide encoded by SEQ ID NO:29.
Group 48. SuperGroup C related to a polypeptide encoded by SEQ ID NO:30.
Group 49. SuperGroup C related to a polypeptide encoded by SEQ ID NO:31.
Group 50. SuperGroup C related to a polypeptide encoded by SEQ ID NO:32.
Group 51. SuperGroup C related to a polypeptide encoded by SEQ ID NO:33.
Group 52. SuperGroup C related to a polypeptide encoded by SEQ ID NO:34.
Group 53. SuperGroup C related to a polypeptide encoded by SEQ ID NO:35.
Group 54. SuperGroup C related to a polypeptide encoded by SEQ ID NO:36.
Group 55. SuperGroup C related to a polypeptide encoded by SEQ ID NO:37.

SuperGroup D: Claims 81-84, drawn to polyketide compositions made by methods for making polyketides using isolated polypeptides that biosynthesize polyketides, classified in class 568, subclass 382.

Group 56. SuperGroup D related to a polypeptide encoded by SEQ ID NO:11.
Group 57. SuperGroup D related to a polypeptide encoded by SEQ ID NO:13.
Group 58. SuperGroup D related to a polypeptide encoded by SEQ ID NO:15.
Group 59. SuperGroup D related to a polypeptide encoded by SEQ ID NO:17.
Group 60. SuperGroup D related to a polypeptide encoded by SEQ ID NO:19.
Group 61. SuperGroup D related to a polypeptide encoded by SEQ ID NO:21.
Group 62. SuperGroup D related to a polypeptide encoded by SEQ ID NO:23.
Group 63. SuperGroup D related to a polypeptide encoded by SEQ ID NO:25.
Group 64. SuperGroup D related to a polypeptide encoded by SEQ ID NO:27.
Group 65. SuperGroup D related to a polypeptide encoded by SEQ ID NO:29.
Group 66. SuperGroup D related to a polypeptide encoded by SEQ ID NO:30.
Group 67. SuperGroup D related to a polypeptide encoded by SEQ ID NO:31.
Group 68. SuperGroup D related to a polypeptide encoded by SEQ ID NO:32.
Group 69. SuperGroup D related to a polypeptide encoded by SEQ ID NO:33.
Group 70. SuperGroup D related to a polypeptide encoded by SEQ ID NO:34.
Group 71. SuperGroup D related to a polypeptide encoded by SEQ ID NO:35.
Group 72. SuperGroup D related to a polypeptide encoded by SEQ ID NO:36.
Group 73. SuperGroup D related to a polypeptide encoded by SEQ ID NO:37.

SuperGroup E: Claim 85, drawn to methods for identifying nucleic acid molecules, classified in class 435, subclass 6.

Group 74. SuperGroup E related to SEQ ID NO:9.
Group 75. SuperGroup E related to SEQ ID NO:11.
Group 76. SuperGroup E related to SEQ ID NO:13.
Group 77. SuperGroup E related to SEQ ID NO:15.
Group 78. SuperGroup E related to SEQ ID NO:17.
Group 79. SuperGroup E related to SEQ ID NO:19.
Group 80. SuperGroup E related to SEQ ID NO:21.
Group 81. SuperGroup E related to SEQ ID NO:23.
Group 82. SuperGroup E related to SEQ ID NO:25.
Group 83. SuperGroup E related to SEQ ID NO:27.
Group 84. SuperGroup E related to SEQ ID NO:29.
Group 85. SuperGroup E related to SEQ ID NO:30.
Group 86. SuperGroup E related to SEQ ID NO:31.
Group 87. SuperGroup E related to SEQ ID NO:32.
Group 88. SuperGroup E related to SEQ ID NO:33.
Group 89. SuperGroup E related to SEQ ID NO:34.
Group 90. SuperGroup E related to SEQ ID NO:35.
Group 91. SuperGroup E related to SEQ ID NO:36.
Group 92. SuperGroup E related to SEQ ID NO:37.

3. The inventions are distinct, each from the other because of the following reasons. The Examiner will first discuss the distinctness between SuperGroups, then the distinctness among members of the SuperGroups.

The DNA of SuperGroup A is related to the corresponding polypeptides of SuperGroup B by virtue of the fact that the DNA encodes the polypeptides. The DNA molecule has utility for the recombinant production of the polypeptides in a host cell. Although the DNA and the polypeptides are related, they are distinct inventions because the polypeptide product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, DNA can be used for processes other than the production of polypeptides, such as nucleic acid hybridization assays. Therefore, corresponding members of SuperGroups A and B are patentably distinct. Members of SuperGroups A and B that do not correspond are unrelated and distinct because of their unique structural and functional features. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The DNA of SuperGroup A is related to the methods of SuperGroup C by virtue of the fact that the DNA encodes the polypeptides used in the methods. However, the DNA of SuperGroup A is distinct from the methods because the DNA is not required to practice the methods since the polypeptides used in the methods can be obtained from non-recombinant sources, such as purification from a natural source. Thus, all members of SuperGroup A are patentably distinct from all members of SuperGroup C. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The DNA of SuperGroup A is related to the polyketide compositions of SuperGroup D by virtue of the fact that the DNA encodes the polypeptides used in the methods to make the polyketides. However, the DNA of SuperGroup A is not required produce the polyketides since the polyketides can be obtained produced by wholly chemical synthesis. Moreover, the polyketides are structurally and functionally distinct compounds from the DNA. Thus, all members of SuperGroup A are patentably distinct from all members of SuperGroup D. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

SuperGroups A and E are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the DNA of SuperGroup A can be used in a materially different process of using that product, such as in recombinant production of the encoded polypeptides. Thus, all members of SuperGroup A are patentably distinct from all members of SuperGroup E. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

SuperGroups B and C are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the polypeptides of SuperGroup B can be used in a materially different process of using that product, such as in recombinant production of the antibodies. Thus, all members of SuperGroup B are patentably distinct from all members of SuperGroup C. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The polypeptides of SuperGroup B are related to the polyketide compositions of SuperGroup D by virtue of the fact that the polypeptides are used in the methods to make the polyketides. However, the polypeptides of SuperGroup B are not required produce the polyketides since the polyketides can be obtained produced by wholly chemical synthesis. Moreover, the polyketides are structurally and functionally distinct compounds from the polypeptides. Thus, all members of SuperGroup B are patentably distinct from all members of SuperGroup D. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The polypeptides of SuperGroup B are related to the methods of SuperGroup E by virtue of the fact that the DNA used in the methods encodes the polypeptides. However, the polypeptides themselves are not used or produced by the methods. Thus, all members of SuperGroup B are patentably distinct from all members of SuperGroup E. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art

as shown by their different classification, restriction for examination purposes as indicated is proper.

SuperGroups C and D are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the polyketide products of SuperGroup C can be made by another and materially different process that is entire chemical synthesis without the help of polypeptides, as in the methods of SuperGroup D. Thus, all members of SuperGroup C are patentably distinct from all members of SuperGroup D. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of SuperGroups C and E are related by virtue of the polypeptides that are used in the methods of SuperGroup C and that are encoded by the DNA used in the methods of SuperGroup E. However, these methods have wholly distinct methods steps with wholly distinct reagents to produce wholly distinct products. Thus, all members of SuperGroup C are patentably distinct from all members of SuperGroup E. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The polyketides of SuperGroup D are related to the methods of SuperGroup E by virtue of the fact that the DNA used in the methods encodes the polypeptides used to make the polyketides. However, the polyketides of SuperGroup D is not required practice the methods

since the methods are drawn solely to hybridization methods without any reference to activity of the polypeptides and/or production of polyketides. Thus, all members of SuperGroup D are patentably distinct from all members of SuperGroup E. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The Groups within SuperGroup A (Groups 1-19) are related to each other as nucleic acids encoding polyketide synthase enzymes involved in polyketide biosynthesis, particularly bryostatin biosynthesis. However, these nucleic acids encode enzymes which each have distinct functional properties catalyzing unique reactions in the biosynthetic pathway of the polyketide bryostatin. Furthermore, these nucleic acids encode enzymes having distinct structural properties with varying amino acid sequence, and thus varying nucleic acid sequence, lacking any consensus among the Groups. Moreover, each of these nucleic acids encode enzymes, or pieces thereof, which can be used in a distinct process from the biosynthesis of the polyketide bryostatin, such as in (1) domain swapping methods for use in other modular PKSs and/or peptide synthetases or in (2) hybridization techniques to identify related PKS genes in other microorganisms. Thus, members of SuperGroup A (Groups 1-19) are patentably distinct, each from the other. While these Groups of DNAs are all identically classified, to search any more than one of the defined Groups would present a search burden on the Examiner based on the extensive searching and evaluation required for any one sequence in the sequence databases as well as patent and non-patent literature text-based databases.

The Groups within SuperGroup B (Groups 20-37) are related polyketide synthase or peptide synthetase enzymes, which are involved in the biosynthetic pathway of polyketides, particularly bryostatin. These enzymes are distinct from each other for the reasons cited above for their encoding nucleic acids. Thus, members of SuperGroup B (Groups 20-37) are patentably distinct, each from the other. While these Groups of polypeptides are all identically classified (which classification may be amended as functions of the polypeptides are noted), to search any more than one of the defined Groups would present a search burden on the Examiner based on the extensive searching and evaluation required for any one sequence in the sequence databases as well as patent and non-patent literature text-based databases.

The Groups within SuperGroup D (Groups 56-73) are related polyketides, which are produced by a polyketide synthase biosynthetic pathway, particularly bryostatin. These polyketides are distinct from each other because of their unique chemical composition as governed by the polyketide synthase enzymes that produced them (see above). Thus, members of SuperGroup D (Groups 56-73) are patentably distinct, each from the other. While these Groups of polyketides are all identically classified (which classification may be amended as specific polyketide structures are noted), to search any more than one of the defined Groups would present a search burden on the Examiner based on the extensive searching and evaluation required for any one compound in the chemical structure databases as well as patent and non-patent literature text-based databases.

The methods of SuperGroup C (Groups 38-55) and SuperGroup E (Groups 74-92) are related, within their respective SuperGroups, as methods of using distinct nucleic acids encoding polyketide synthase biosynthetic enzymes, or the distinct enzymes themselves, which together

can produce bryostatin-like polyketides. The methods within each SuperGroup are distinct from every other method in the SuperGroup for the reasons cited above for the distinctness of the nucleic acids and/or the enzymes. Thus, members of SuperGroup C (Groups 38-55) are patentably distinct, each from the other. Members of SuperGroup E (Groups 74-92) are patentably distinct, each from the other.

Notice of Possible Rejoinder

4. The Examiner notes that if product claims in SuperGroups A, B or D are found directed to an allowable product, then process claims in SuperGroups C or E, which are directed to processes of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

- Method SuperGroup C is a method of using a polypeptide of SuperGroup B and a method of making the polyketides of SuperGroup E.
- Method SuperGroup E is a method of using a DNA of SuperGroup A.

Election

5. A telephone call was made to Warren Woessner on September 10, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

6. Claims 66-89 have been restricted. A complete response to the instant Office action must include and election of an invention (Group) to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
September 10, 2002